

I. Remarks

A. Status of the Claims

Claims 1, 4-7, 9-10, 14-17, 21, 23-24, 32-43, 47, 51, and 54-56 are cancelled herein.

Claims 3, 6-8, 11-13, 18-20, 22, 26-30, 44-46, 49-50, and 52-53 are pending in the Application.

New Claims 57-78 are added herein.

The claims pending in the Application are all amended to recite a “method” rather than a “process”. Although the terms “process” and “method” are synonymous, it is common practice in claim drafting to refer to treating an animal or human or to administering an active agent to an animal or human as a method rather than a process.

As demonstrated by the Table presented below, the newly added claims are fully supported by the specification and claims as originally filed.

| New Claim No. | Corresponds To Original Claim No. | Support In Specification | Comments   |
|---------------|-----------------------------------|--------------------------|--|
| 57            | 1, 23-24, and 37-38               |                          | The subject matter of the listed original claims was combined into new Claim 57.   |
| 58            | 1, 23-24, and 37-38               |                          | The subject matter of the listed original claims was combined into new Claim 58.   |
| 59            | 24                                |                          |  |
| 60            | 26                                |                          |  |
| 61            | 27                                |                          |  |
| 62            | 23 and 37                         |                          |  |
| 63            | 36                                |                          |  |
| 64            |                                   |                          |  |
| 65            | 23 and 38                         |                          |  |
| 66            | 40                                |                          |  |
| 67            |                                   | [0016] [0019]            |  |
| 68            |                                   | [0030]                   |  |
| 69            |                                   | [0031]                   |  |
| 70            |                                   | [0022]                   |  |
| 71            |                                   | [0016]<br>[0019]         |  |
| 72            | 41                                |                          |  |
| 73            |                                   | [0031]                   | Subject matter is a combination of new Claim 57, New Claim 67, and [0031] of the specification   |
| 74            |                                   | [0022]                   |  |
| 75            |                                   |                          | Subject matter is a combination of new Claim 57, New Claim 67, paragraph [0031] of the specification and paragraph [0030] of the specification |
| 76            | 56                                | [0040]<br>[0047]         |  |
| 77            |                                   | [0047]                   |  |
| 78            | 20                                | [0031]                   |  |

New Independent Claim 57 and Independent Claim 73 use the phrase “charged aerosol particles” to refer to what the claims as originally presented referred to as “charged material”. The pending original claims were amended to specify that what is being produced by the electrohydrodynamic (“EHD”) means is an aerosol. This change is fully supported by the specification at paragraphs [0016] and [0017]. Further, as would be recognized by one skilled in the EHD art, and as taught by Thurston et al referenced at [0032] of Applicants’ specification, the term “particle” or “particles” as used in [0016] and [0017] of Applicants’ specification refers to an aerosol particle. Examiner’s attention is directed to Col. 2, lines 38-45 and Col. 3, lines 19-67, and Col.4, lines 1-6 of Thurston et al. (US Pat 6503481).

The term “active agent” is used in new Independent Claim 57 and Independent Claim 73 to refer to pesticides, therapeutic agents and cosmetic agents. Although, the term “active agent” is not used in Applicants’ specification, the term “additive” is used in, e.g., original Claim 23 to collectively refer to “pesticides, therapeutic agents, and cosmetics”. Applicants believe that the term “active agent” is a more descriptive and/or more understandable term for the claimed agents being used in the method of Applicants’ invention. Applicants stand ready to amend Claims 57 and 73 to use the term “additive” if Examiner requests.

The amendments to the original claims as well as the newly added claims are supported by the specification, by the claims as originally filed and by the general knowledge of one skilled in the art of EHD aerosolization, and do not add any new matter to the claims. Further, the subject matter of the amended claims and the newly added claims was present in the claims as originally filed and as such has been searched by the Examiner and therefore, would not require any further searching on the part of Examiner.

The subject matter of the cancelled claims has not been abandoned by Applicants and Applicants reserve the right to file one or more continuation applications to this subject matter.

**B. Petition for Extension of Time**

Accompanying this Response is a Petition for Extension of Time (PTO/SB/22) for a 3-month extension of time as well as the required fee.

**C. Claims Objections**

Claim 1, 17, and 32 are objected to because they use the acronym “EHD”. These claims are cancelled herein obviating Examiner’s objection to these claims. However, new independent Claim 57 and new independent Claim 73 provide the proper term “electrohydrodynamic” and then give this term its

acronym "EHD". Accordingly, Examiner should have no further objection to any of the pending claims on this ground.

Claim 17 has been cancelled obviating Examiner's objection to this claim for failing to recite the proper dependency.

Claim 32 is cancelled herein obviating Examiner's objection to Claim 32 for reciting the term "earners" instead of "carriers".

#### I. Applicants' Invention

Applicants' invention in its broadest embodiment is directed to a method (process) for treating a non-human animal comprising the steps of creating charged aerosol particles containing at least one active agent, wherein said charged aerosol is created using electrohydrodynamic ("EHD") means and thereafter applying said charged aerosol to the surface of said animal and wherein said aerosol particles have a diameter greater than that respirable by a human.

#### II. The References

Coffee I describes and claims an EHD device which is adapted to deliver charged or partially discharged droplets (aerosol particles). The reference specifically teaches that the device is preferably used as a nasal spray. (Col 2, line 63) Coffee I teaches at Col.1, lines 46-50 that "[w]e have ... discovered that electrohydrodynamic spray technology may be used to deliver charged or partially charged monodisperse liquid droplet sprays, especially medicament sprays, to the upper respiratory tract and especially to the nasal mucosa, in an efficient and very controllable manner." The EHD device described by Coffee I produces an aerosol from a liquid where the particle size diameter of the aerosol droplet ranges from 10  $\mu\text{m}$  to about 500  $\mu\text{m}$  and preferably from about 10 $\mu\text{m}$  to about 200  $\mu\text{m}$  in diameter.

The Coffee II reference adds little to the disclosure of Coffee I. Coffee II describes and claims an EHD aerosolization means with 2 comminution sites rather than the single site disclosed by Coffee I. The reference teaches that the device is preferably configured to be in the form of an inhaler for delivering drugs to the respiratory tract of a patient. Col.4, lines 46-67. Since the medicament being aerosolized is being delivered to the respiratory tract of a patient the particle size diameter of the aerosol particle ranges from 0.1  $\mu\text{m}$  to about 25  $\mu\text{m}$  (See Claims 2 and 7-9).

The Maget reference describes a device which delivers a liquid by pushing the liquid from the device using a gas. The liquid containing an active agent is deposited on an absorbent pad which may

be a transdermal pad or an evaporation pad. When the pad is a transdermal pad, the pad is placed on the human or animal patient and the device is placed on top of the pad and attached to the human or animal. The patient wears the device as it is depositing the liquid. Once the liquid containing the active agent is deposited on the transdermal pad, the liquid seeps out of the pad onto the skin of the human or hide of an animal. When the pad is an evaporation pad, the vapors of the active agent escape into the air around the device.

Matthews (US Pat 4334504) describes a set-up for spraying an active agent, e.g., an insecticide on to an animal as it moves through a passageway. Only one side of the animal is sprayed with the liquid as it moves through the passageway. The animal must be led back through the passage way in the opposite direction in order that the other side of the animal's body may be sprayed.

Ramsey et al (US Pat 6029610) describes and claims an apparatus for washing animals such as sheep prior to slaughter. The animal to be washed is sent from a holding pen through a passageway and into an area where the animal is sprayed allover its body with a detergent solution. The animal is then moved to a holding area where it is kept for a period of time to allow the detergent solution to work and thereafter the animal is sprayed again to rinse off the detergent solution. The detergent solution is sprayed on the animal from multiple spray bars as shown in Fig. 3 of the reference.

Franklin et al (US Pat 6130253) describes and claims various formulations, e.g., lotions, shampoos, gels, dips and drenches for treating terrestrial arthropods such as head lice, body lice and pubic lice and mites such as house dust mites. The preferred embodiment of the invention (Col 20, lines 64-66) is a pesticidal shampoo. The active agents in the pesticidal formulations are terpenes selected from the group including limonene, beta-ionone, linalool, geraniol, eugenol, and myrcene or carvone.

Sembo et al (US Pat 6201017) describes certain ectoparasite-controlling compounds which are neonicotinoid compounds as well as topical formulations containing such active agents and methods for using such formulations. The ectoparasites are fleas, lice and ticks which infest farm animals and companion animals. The liquid formulation disclosed by Sembo comprises 10 to 95% by weight of a glycol or glycol monoalkyl ether (e.g. C<sub>1-4</sub> alkyl ether) and 0.1 to 20% by weight of the neonicotinoid compound, and may comprise, optionally, for example, liquid carriers such as C<sub>1-4</sub> alcohols, benzyl alcohol, propylene carbonate, N-methyl-2-pyrrolidone and water; auxiliaries such as anti-oxidants such as BHT and BHA; emulsifiers such as sorbitan monooleate, sorbitan monolaurate, caprylic acid monoglyceride, capric acid monoglyceride, isostearic acid monoglyceride and propylene glycol monocaprylate; and oxyacid esters such as triethyl citrate. The formulations of Sembo may also contain active ingredients other than the neonicotinoids.

The formulation of Sembo is applied to the animal as either a spot-on application or a pour-on application. The spot-on application is a well-known method for controlling ectoparasites by dropping a liquid agent onto a skin at the back of blade bone of animal body. The pour-on application is also a well-known method for controlling ectoparasites by pouring a liquid agent along the back line of the animal body and having the liquid agent spread on the surface of the animal body.

Dvorsky et al (US Pat No 6302331) describes an electrohydrodynamic (EHD) aerosolization device that permits an operator to consistently aerosolize a liquid horizontally or in any other arbitrary direction, in the absence of other external airflow. The device utilizes electrical means for stabilizing the Taylor cone with a gas flow near the Taylor cone and for directionally controlling the movement of the charged aerosol generally in a direction controlled by the position and orientation of the discharge electrode and the reference electrode. The aerosol delivery system and method are particularly useful for delivering therapeutic agents by inhalation into the lungs. The charged aerosol is neutralized by a cloud of positively charged ions. Dvorsky teaches that the movement of the negatively charged aerosol away from the discharge electrode is due to the effect of what is termed a corona wind or induced air flow. Dvorsky theorizes that the corona wind works in the following way. The positive charge on the discharge electrode results in corona or ionization of the nearby air molecules producing a positive ion cloud around the electrode. The like-charged ions repel and cause a migration of these ionized air molecules away from the discharge electrode. Since these air molecules have mass, their movement causes a corona wind effect or induced air flow directly away from the discharge electrode, which then intercepts the aerosol droplets downstream of the tip of the nozzle and redirects them (imparts momentum) generally along the path of the corona wind. The positively charged air molecules also serve to neutralize/discharge the negative charge on the aerosol.

#### IV. Rejections Under 35 U.S.C §103(a)

Examiner has made three (3) separate Section 103(a) rejections against Applicants claims; these rejections are as follows:

Rejection 1. Claims 1, 3, 5-9, 12-24, 26-30, 32, 37-47, and 49-56 are rejected under Section 103(a) as being obvious over US Pat. 5,655,517 (Coffee I), US Pat. 6,105,877 (Coffee II), US Pat. 5,928,194 (Maget), and US Pat. 4,334,504 (Matthews).

Rejection 2. Claims 1, 3, 5-24, 26-30, 32, 33, 37-47 and 49-56 are rejected as obvious over US Pat. 5,655,517 (Coffee I), US Pat. 6,105,877 (Coffee II), US Pat. 5,928,194 (Maget), and US Pat.

4,334,504 (Matthews), and further in view of US Pat. 6,029,610 (Ramsey), US Pat. 6,130,253 (Franklin et al.), and US 6,201,017 (Sembo).

Rejection 3. Claims 1-9, 12-22, 41-46, and 52 are rejected under Section 103(a) over over US Pat. 5,655,517 (Coffee I), US Pat. 6,105,877 (Coffee II), US Pat. 5,928,194 (Maget), and US Pat. 4,334,504 (Matthews) in view of US Pat. 6,302,331 (Dvorsky at al.).

A. First Section 103(a) Rejection

Examiner contends that the references teach the following:

Coffee I teaches single nozzle EHD delivery devices for delivery of substances by "spray" into the respiratory tract ...to avoid the lower respiratory tract of humans, particles should be 10 microns or above;

Coffee II teaches dual nozzle devices for similar delivery of substances;

Maget teaches a liquid spray dispenser for dispensing ... insecticides and therapeutics transdermally to horses; and

Matthews teaches an animal spraying apparatus, which applies liquids to the surface of the animal as it moves back and forth through the passageway.

Examiner concludes that, "...at the time of invention, it would have been obvious to apply the Mathews '504 apparatus, in combination with the EHD delivery device(s) of Coffee, and do so to horses, as further taught in Matthews." Examiner goes on to assert that, "[b]ecause the references teach similar methods of spraying animals to obtain various therapeutic and cosmetic alterations, it would have been obvious to the Artisan to utilize any combination of these elements to provide the predictable result of distributing one or more therapeutics and/or cosmetics to the animal without allowing the particles to enter the lower respiratory tract of humans."

The Coffee references are concerned with aerosolization of liquids containing medicaments using electrohydrodynamic ("EHD") aerosolization devices. However, neither of the Coffee references teach the methods of Applicants' invention. Coffee I is directed to a device that is used as a means to deliver a nasal spray to release an aerosol into the nasal passages of a patient. This reference does not teach or suggest a method for delivering active agents to the surface of an animal. Further, although Coffee I describes the production of an aerosol having a broad particle size range, i.e., from 10 to about 500 um in

diameter, as would be recognized by one skilled in this art, in actual practice, aerosol particle diameters greater than about 30-50  $\mu\text{m}$  would be expected to coalesce in the nose to form larger drops which would drip out of the nose wasting drug.

The Coffee II reference describes a different type of EHD device from the device of Coffee I. The Coffee II device is configured so as to be used by a patient as an inhaler to deliver a medicament containing aerosol to the respiratory tract of a patient and especially to the deep lung. The Coffee II reference does not describe or suggest Applicant's claimed methods. In Applicants method the aerosol particles containing the active agent are required to be non-respirable. In contrast, the aerosols produced by the EHD device of Coffee II are required to be respirable.

The Magat reference neither teaches aerosolization of a liquid, or application of an aerosol to the surface of an animal, or electrohydrodynamic aerosolization of liquids. The device of Magat delivers a liquid when it is placed on (i.e., attached to) a human or animal. The Magat device is designed to be attached to the human/animal as the liquid is being delivered. The device fits over a transdermal pad and both of these elements are attached to the human/animal in the following order: device, transdermal pad, skin or hide of human or animal. Once the device is activated it delivers drops of liquid to the transdermal pad and the liquid seeps through the pad to the skin of the human or hide of the animal. The human or animal is free to move around while wearing the device and while the active agent is being delivered through the transdermal pad.

There are significant differences between the invention described and claimed in the Magat reference and the invention claimed by Applicants. First of all, the Magat device does not produce an aerosol much less an aerosol having a charge. The configuration of the Magat device is such that the liquid containing the active agent is first delivered to a transdermal pad and from the pad to the skin or hide of the human or animal being treated. In contrast, Applicants claimed method delivers a soft cloud of charged aerosol particles to air around the animal and the charge on the particles causes the aerosol to be attracted to the surface of the animal. The differences between the technology of Magat and that of Applicants is so great that one skilled in the art of EHD aerosolization would not consider Magat to be pertinent prior art.

The Matthews reference describes a relatively large apparatus which is set up in a "passageway" through which a farmer or rancher drives livestock. A liquid containing an active agent, e.g., an insecticide is sprayed onto one side of the animal as it moves through the passageway; the animal is moved back through the passageway in order to spray the other side of the animal. There is nothing in the Matthews reference which is concerned with the art of aerosolization much less with aerosolization using EHD

means.

Applicants did a forward reference search on the Matthews patent to see what patents have cited the reference. Since the Matthews patent issued in 1982, only six (6) references have cited Matthews. All of these references have to do with spraying or cleaning animals using fluids not aerosols. For example, the most recent reference to cite Matthews is US Pat. 6382136 to Bragulla et al.

The '136 patent describes a 2-stage method where in a first stage, the animals' hooves are cleaned with water or a different soap- or surfactant-containing cleaning product using an automatic spray system to remove all traces of excrement, in particular manure or other dirt, and, in a second stage, the previously cleaned animals' hooves are treated by wetting or spraying with a disinfectant.

Although Examiner asserts that "arguments implying the need for specific motivation are no longer considered by the Office", the level of skill in the art is certainly still a consideration. The skilled artisan of Matthews is likely a farmer or rancher. The skilled artisan of Bragulla may be a large scale dairyman or stockman but the level of skill is still that of a skilled farmer, rancher or dairyman. In contrast, the level of skill in the art of aerosolization using electrohydrodynamic aerosolization means is quite different.

The art of aerosolization requires an understanding of surface tension and the use of materials such as surfactants to affect interfaces (e.g., liquid/air). When using an electrohydrodynamic means to aerosolize a liquid, the level of skill must include knowledge of the application of a charge to the surface of a liquid being aerosolized in order to promote the formation of a so-called Taylor cone. The cone shape results from a balance of the forces of electric charge on the fluid being aerosolized and the fluid's own surface tension. The charge on the fluid overcomes the surface tension and at the tip of the Taylor cone, a thin jet of fluid forms and subsequently and rapidly separates a short distance beyond the tip into an aerosol.

The qualifications of, and the level of skill of, one of ordinary skill in the art of aerosolization using electrohydrodynamic means requires that the artisan have a much higher level of skill than that required of a skilled farmer or rancher. The level of skill required for EHD aerosolization is much higher than that required to spray a farm animal e.g., cattle or sheep moving through a passage way. Accordingly, one skilled in this art would not consider the Matthews reference to be relevant prior art.

**B. Second Section 103(a) Rejection**

Claims 1, 3, 5-24, 26-30, 32, 33, 37-47, and 49-56 are rejected under 35 USC §103(a) as being unpatentable over Coffee I, Coffee II, Magat, and Mathews and further in view of Ramsey, Franklin and Sembo.

Examiner contends that "... it would be obvious to include the shampoos of Ramsey at the same time and include the pyrethroids and neonicotinoids of Sembo and Franklin."

The Ramsey reference describes and claims an apparatus for washing animals such as sheep prior to slaughter. The animal to be washed is sent from a holding pen through a passageway and into an area where the animal is sprayed all over its body with a detergent solution. The animal is then moved to a holding area where it is kept for a period of time to allow the detergent solution to work and thereafter the animal is sprayed again to rinse off the detergent solution.

As discussed above, the qualifications of, and the level of skill of, one of ordinary skill in the art of aerosolization using electrohydrodynamic means requires that the artisan have a much higher level of skill than that required of the operator of a slaughter house. Accordingly, one skilled in the art of EHD aerosolization and methods of using aerosols produced by EHD aerosolization would not consider the Ramsey reference to be prior art at all because the level of skill required for EHD aerosolization is much higher than that required to spray a farm animal e.g., cattle or sheep moving through a passage way in a slaughter house.

The Franklin reference describes and claims various formulations, e.g., lotions, shampoos, gels, dips and drenches for treating terrestrial arthropods such as head lice, body lice and pubic lice and mites such as house dust mites. The preferred embodiment of the invention of Franklin is a pesticidal shampoo. The disclosure of Franklin does not add anything to Examiner's Section 103 rejection of Applicants claims.

Applicants are claiming a method of applying certain aerosols produced by EHD aerosolization to the surface of companion animals. There is no disclosure in the Franklin reference even remotely related to EHD aerosolization. Applicants are not claiming any specific active agents *per se* but rather the use of such active agents in the methods of Applicants' invention. Further, one skilled in the art of EHD aerosolization would not be led to use the shampoos, lotions, gels etc. disclosed by Franklin in the methods of Applicants' invention as there is no reason to believe that any of the specific formulations of

Franklin would be capable of being sprayed using EHD means. The Franklin lotions or shampoos may be too viscous to efficiently spray using EHD means or such a high voltage would be necessary to produce the Taylor cone that it would be impractical to spray (aerosolize) using EHD means.

While the teachings of Franklin might be combined with the teachings of Matthews and Ramsey to arrive at a shampoo, drench or dip useful in the spraying apparatus of Matthews and Ramsey, there is no reason one skilled in this art would consider the teachings of Franklin to be relevant to the invention claimed herein.

Sembo et al describes certain ectoparasite-controlling compounds which are neonicotinoid compounds as well as topical formulations containing such active agents and methods for using such formulations. The formulation of Sembo is applied to the animal as either a spot-on application or a pour-on application. The spot-on application is a well-known method for controlling ectoparasites by dropping a liquid agent onto a skin at the back of blade bone of the animal body. The pour-on application is also a well-known method for controlling ectoparasites by pouring a liquid agent along the back line of the animal body and having the liquid agent spread on the surface of the animal body.

As discussed above in connection with the Franklin reference, Applicants' invention is directed to a method rather than to active agents *per se*. The question is would one skilled in the art of EHD aerosolization find any information in the Sembo reference that would render Applicants' claimed method obvious? The answer is clearly no. The Sembo reference teaches nothing about producing an aerosol using EHD means where such aerosol is non-respirable by a human and applying such aerosol to the surface of an animal; accordingly, the Sembo reference adds nothing to Examiner's obviousness rejection of Applicants claimed methods.

#### C. Third Section 103(a) Rejection

Claims 1-9, 12-22, 41-46, and 52 are rejected under Section 103(a) over Coffee I, Coffee II, Magat, and Mathews in view of Dvorsky et al.

Examiner states that although Coffee I and II and Magat and Mathews make obvious the various aspects of the previously-rejected claims they do not make obvious the use of an EHD device to deliver uncharged particles. Examiner cites the Dvorsky reference as teaching delivery of uncharged particles.

Applicants disagree that Coffee I, Coffee II, Magat and Matthews make obvious Applicants' claimed method. However, Examiner is correct that Dvorsky describes the use of a particular EHD device to produce uncharged particles for delivery to the lungs of a human.

The references of record dealing with EHD aerosolization means are Coffee I, Coffee II and Dvorsky. The Dvorsky reference describes a different EHD means than that disclosed by Coffee I and Coffee II.

Coffee I teaches that he has discovered that electrohydrodynamic spray technology may be used to deliver charged or partially charged monodisperse liquid droplet sprays, especially medicament sprays, to the upper respiratory tract and especially to the nasal mucosa, in an efficient and very controllable manner. The Coffee II reference adds little to the disclosure of Coffee I. This reference describes and claims an EHD aerosolization means with 2 comminution sites rather than the single site disclosed by Coffee I. The reference teaches that the device is preferably configured to be in the form of an inhaler for delivering drugs to the respiratory tract of a patient.

Dvorsky teaches an EHD aerosolization device that permits an operator to consistently aerosolize a liquid horizontally or in any other arbitrary direction, in the absence of other external airflow. The aerosol delivery system and method are particularly useful for delivering therapeutic agents by inhalation into the lungs. The charged aerosol is neutralized by a cloud of positively charged ions.

All of the EHD references describe the production of aerosols that are respirable by the patient being treated. There is no specific recognition in any of these references regarding methods of applying non-respirable aerosols containing an active agent to the surface of an animal.

#### D. Applicants Arguments

It is respectfully asserted that Examiner has failed to make out a case of obviousness of Applicants' presently claimed invention. The references of record relating to the art of EHD aerosolization (Coffee I, Coffee II and Dvorsky) taken together fail to render obvious Applicants' claimed invention or Examiner would not have had to shore up his obviousness rejection using references that are not remotely connected to aerosolization, much less EHD aerosolization.

The Matthews and Ramsey references are not remotely related to aerosolization of liquids using an EHD device or to a method of using such aerosols to deliver active agents to the surface of an animal. Both Matthews and Ramsey teach an apparatus for either applying a liquid insecticide to an animal or applying a soap or detergent to an animal prior to slaughter. These apparatuses are not

remotely similar to an EHD device. Accordingly, one skilled in the art of EHD aerosolization and methods of using aerosols produced by EHD aerosolization would not consider either the Ramsey reference or the Matthews reference to be relevant prior art.

There are significant differences between the invention described and claimed in the Magat reference and the invention claimed by Applicants. First of all, the Magat device does not produce an aerosol much less an aerosol having a charge. The configuration of the Magat device is such that the liquid containing the active agent is first delivered to a transdermal pad and from the pad to the skin or hide of the human or animal being treated. In contrast, Applicants claimed method delivers a soft cloud of charged aerosol particles to air around the animal and the charge on the particles causes the aerosol to be attracted to the surface of the animal. The differences between the technology of Magat and that of Applicants is so great that one skilled in the art of EHD aerosolization would not consider Magat to be pertinent prior art.

Neither the Franklin or the Sembo reference describe the production of any aerosol much less an aerosol using EHD means and applying such aerosol to the surface of an animal. These references add nothing to Examiner's obviousness rejection of Applicants claimed methods.

It is respectfully contended that based on the arguments and discussion presented herein, Applicants' have overcome all of the Section 103(a) obviousness rejections. Accordingly, the rejections of Applicants' claims under 35 USC §103(a) have been overcome and such rejections should be withdrawn.

#### IV. Obviousness Double Patenting Rejection

Examiner has rejected Applicants' claims on the grounds of obviousness double patenting. Specifically Examiner makes the following rejections:

1. Claims 1-33, 36-47 and 49-56 are rejected over claims 1-13 of US Pat 5,655,517 (Coffee I);
2. Claims 1-33, 36-37 and 46-56 are rejected over claims 1-15 of US Pat. 5,813,614;
3. Claims 1-33, 36-37 and 46-56 are rejected over claims 1-13 of US Pat. 5915377;
4. Claims 1-33, 36-37 and 46-56 are rejected over claims 1-7 of US Pat. 6,105,571;
5. Claims 1-33, 36-37 and 46-56 are rejected over claims 24-26 of US Pat. 6,252,129;
6. Claims 1-33, 36-37 and 46-56 are rejected over claims 1-15 of US Pat. 6,386,195; and
7. Claims 1-33, 36-37 and 46-56 are rejected over claims 1-52 of US Pat. 6,595,208.

Obviousness-type double patenting is a judge-made criterion adopted out of the necessity where the courts were faced with a situation in which claims in an application and patent were not drawn precisely to the same invention, but were drawn to claimed inventions so very much alike as to render one obvious in view of the other and to effectively extend the life of the patent that would have the earlier of the two issue dates. *Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 16 USPQ2d 1436 (Fed. Cir. 1990).

An obviousness-type double patenting analysis, involves a factual determination regarding whether the claims of the subsequent patent (application) represent simply a mere variation over the claims of the earlier patent; it is very specific. It compares a subsequent patent to a previous one issued to the same inventor. By contrast, obviousness under Section 103 is general; it compares a new patent to all prior art. *Refac International Ltd. v. Matsushita Electric Corp. of America*, 17 USPQ2d 1293, 1299 (D.N.J. 1990).

The court held in *In re Bartfeld*, 17 USPQ2d, 1885, 1888 (Fed. Cir. 1991), that “[t]he obviousness-type double patenting rejection and the §102(e)/103 rejections may be analogous in the sense that an obviousness analysis is performed in both cases, but they are not analogous in terms of *what* is analyzed. [Emphasis in Original] The test is not whether the second patent’s claims would be obvious to one of ordinary skill in the art from reading the specification and claims of the first patent. The inquiry is more limited – the question is whether the “tangible embodiment” of a claim in the first patent has been modified in an obvious manner. See *Sarkisian v. Winn-Proof Corp.*, 203USPQ 60 (D. Ore. 1978) *rev’d on other grounds*, 697 F. 2d. 1313, 217 USPQ 702 (9<sup>th</sup> Cir. 1983), *cert. denied sub nom.*

Issuance of Applicants’ claims would not prolong the monopoly, i.e., the right to exclude others by the assignee of the patents listed above. The reason for this is that a third party would not infringe Applicants’ claimed invention (assuming claims issue) by practicing any of the device claims listed above. Applicants’ claims are not a “mere variation” over the device claims of the patents listed above.

In making an obviousness-type double patenting rejection, the claims of the earlier patent are compared to the claims of the application. All of the cited claims in the patents listed above are directed to variants of an EHD device. Applicants’ claims are directed to a method of applying an active agent in the form of an aerosol to the surface of an animal. Issuance of Applicants’ claims would not prolong the monopoly, i.e., the right to exclude others) of the assignee of the patents listed above because the claims are directed to entirely different subject matter. If after the patent expires, a third party practiced the device claims of, e.g., the ‘517 patent listed above, such third party would not infringe Applicants’ claimed invention (assuming claims issue). Practice of device claims by a third party would not infringe claims

directed to a method and Applicants' claims are not a "mere variation" over the device claims of the patents listed above.

Based on the arguments presented above, it is respectfully asserted that Examiner's obviousness-type double patenting rejection is in error and should be withdrawn.

**V. Conclusion**

Based on the amendments and arguments made herein, it is respectfully asserted that Examiner's rejections have been overcome and that this application is in condition for allowance. Examiner is respectfully requested to withdraw all rejections and to issue a Notice of Allowance. If there are any questions regarding these amendments and remarks, Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

By: Patricia A. Coburn

Name: Patricia A. Coburn

Date: August 28, 2008

Reg. No. 28,594